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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,488	01/16/2002	Shen-Chun Kuo	CD01351	7695

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/050,488

Applicant(s)

KUO ET AL.

Examiner

Venkataraman Balasubramanian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 25-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-12 and 14-23 is/are rejected.
- 7) ☒ Claim(s) 9, 13 and 24 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: .

DETAILED ACTION

Claims 1-30 are pending.

Applicant's election with traverse of Group I, claims 1-24 in Paper No. 5 is acknowledged. In view of applicants pointing out an error in excluding claims 28-30 in restriction requirement, a revised restriction requirement as shown below is made.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-24, drawn to a process of making bicyclotetrazine of formula shown in claim 1, and process of making its intermediates, classified in class 544, subclass 179, class 548, subclass 326.5, class 558, subclasses 426, 452.
- II. Claims 18-20, 26, drawn to intermediate compound of formula II, III, V and compound 8, 6, 5, and their acid addition salts classified in class 544, subclass 179, class 548, subclass 326.5, class 558, subclasses 426, 452.
- III. Claims 18-20, 25-26, drawn to compound of formula VI and compound 4, its acid addition salt, classified in class 558, subclass 426.
- IV. Claims 18-20, 27, drawn to compound of formula IV and compound 13, its acid addition salts, classified in class 558, subclass 452.
- V. Claims 20, 26, drawn to compound 17 and its acid addition salt, classified in class 548, subclass 326.5.
- VI. Claims 28-29, drawn to processes for making 4-amino-5-imidazole carboxamide, classified in class 548, subclass 326.5.

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VII. Claim 30, drawn to processes for making 3-substitutedcarboxamido-4-amino-5-imidazole carboxamide, classified in class 548, subclass 326.5.

The inventions are distinct, each from the other because of the following reasons:

Inventions II, III, IV and V are independent and distinct from each other because they are directed to dissimilar compounds varying core such as bicyclotetrazine, imidazole, oximino or aminonitriles. Consequently, the groups have different classifications and require separate prior art searches. Their method of making and their uses are distinct as evidenced by applicants' specification and several references cited in the Information Disclosure Statement. See all Wang et al. references, Lunt et al and Stevens et al. Art, which may render obvious or anticipate one of the groups would not necessarily do the same for the other group. Each can support a patent, as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group. In addition, searching all intermediates classes/subclasses, which is a mandatory, would be a serious search burden given limited time available for examination of each application.

Inventions I & II-V are related as intermediate products and process of using these intermediate products to make the final bicylcotetrazine, which is a known prior art compound. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using these intermediate products as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of making the compound of claim 1 can be can be practiced with another materially different product. See references cited in the IDS. Similarly, it is

clear from the claims that the process of using can be practiced with materially different products (see Lunt et al. and Stevens et al.).

Similarly, invention VI and VII relate to process of making 4-amino-5-carboxamidoimidazole with or without a substituent on the 3-Nitrogen. The process of making them are as can be seen is distinct. For example, 4-amino-5-carboxamidoimidazole can be made by different process as evidenced by claims 28 and 29 as well as references cited in the IDS. The process of making the compound shown in claim 30 need not be same as those required for process 28 and 29.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with William Lee on 8/7/2003 a provisional election was made with traverse to prosecute the invention of Group I, claim 1-24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 25-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 1-24 would be examined to the extent they embrace the elected subject matter.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Applicants' traversal that the claims taken together embrace a same common invention is incorrect and is not persuasive for reasons of record. In addition, as seen clearly, the process of making the known compound Temozolomide is clearly distinct from the process of making the intermediate imidazole compound of claims 28, 29 or 30. Similarly, the intermediates may not be known in prior art whereas Temozolomide is a known compound and they do not share same use.

Hence, the restriction is proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 10-12, and 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baig et al. GB 2 125 402.

Baig et al. discloses a compound of formula I shown on figure I and process for making the compound, which includes the process claimed herein. See Figure I on page 19 and note the definition of various variable groups. Particularly note when R^2 is $CONR^7R^8$ the compounds taught and the process for making includes instant process and compound. Especially note R^7 can be hydrogen or an alkyl, while R^8 can be hydrogen, alkyl or optionally substituted benzyl, which qualify as a protecting group. See examples 1-28 shown on pages 4-10.

Instant claims differ from the reference in reciting the Pg" as protecting group while the reference includes them as groups whose presence also results in the claimed activity. In addition, when R^7 and R^8 are hydrogen, the compound is taught to be active. It is known in the art and hence omitted in the specification such groups can be easily removed. For example the benzyl group can be removed by hydrogenolysis.

Instant claims also require a process of making the imidazole intermediate.

The secondary reference Chabala et al. teaches a process for making the said imidazole compounds. See formula shown on page 2 and note the definition of R_1 , R_2 ,

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R₃, and R₄ groups. See reaction scheme 2 on page 9 and examples 1-4 and Table 1 for various imidazole compounds made.

Thus one having ordinary skill in the art at the time of the invention was made would have been motivated to combine both the primary reference, secondary reference, and what is known in the prior art and employ the process taught by these prior art to the starting materials and reactants of the instant invention and expect to obtain the desired product because he would have expected the analogous starting materials and reactants react similarly. It has been held that application of an old process to an analogous material to obtain a result consistent with the teachings of the art would have been obvious to one having ordinary skill. Note *In re Kerkhoven* 205 USPQ 1069.

Allowable Subject Matter

Claims 9,13 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable, barring finding of any additional prior art, if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Said claims would be allowed since specific limitation embraced in these claims are not taught or suggested by the art of record or from a search in the relevant art area.

References cited in the Information Disclosure Statement (paper # 2) are made of record.

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Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Venkataraman Balasubramanian

8/7/2003